REMARKS

1. Remarks Concerning the Drawing Objection

In the non-compliant response submitted on August 14, 2006, Applicants enclosed therein new formal drawings comprising Replacement Sheets 1-7. In addition to curing the general objections to the drawings, the specific objection to the numeral 62 in Figure 1 has been cured by its deletion as shown in the Figures. Applicants presume that the Replacement Sheets 1-7 submitted on August 14, 2006 cured the drawing objections and as such, do not submit additional copies here.

2. Remarks Concerning the Objection to the Specification

Applicants have amended Figure 1 of the drawings by deleting reference numeral 62 in Figure 1, thus curing the objection to the specification.

3. Remarks Concerning the Office Action

a. Rejection of claims 1-4 as anticipated by U.S. Patent No. 6,402,734 to Weiss

Claims 1-4 stand rejected as anticipated by Weiss. Applicants traverse this rejection. Independent claim 1 is not anticipated by Weiss and thus claims 1-4 are allowable thereover.

In the Office action it is stated that Weiss includes a probe "having a passage therein configured to conform at least in part to the curvature of the eye (col. 3., ll. 50-64)". Applicants do not claim a "passage configured to conform at least in part to the curvature of the eye" but instead a "probe ... [that] is configured to conform at least in part to the curvature of the eye... ." Thus, the rejection on the basis of Weiss can not stand for this reason alone.

The Weiss probe comprises two straight probe segments joined at a single angle ("the opening (2) that is preferably connected to a surgical tubing and the tip (3) of the micropipette oriented at an approximately 135 degree angle, although other ranges are possible. Tip (3) is angled so that it may safely cannulate the retinal vessel when

micropipette (1) is placed through a standard retinal surgical sclerotomy site." Weiss at col. 3, ll.22-28). The Weiss Figures simply do not show a probe that is configured to conform to the eye's curvature.

In an event, an examination of the cited passage does not support the passage cited in the Office action. At no point at the location cited by the Office does Weiss discuss the configuration of the probe/passage, let alone that it is structured to conform to the eye's curvature. In fact, Weiss has no need to include a probe having a portion thereof configured to conform to the eye's curvature.

Weiss's system can be said to be "minimally invasive" only to the extent of comparison of its use to past practices. Weiss's system requires an incision be made in the eye into which his apparatus is manipulated so as to treat the retinal blood supply.

In contrast, Applicants invention is truly minimally invasive in that no such incision is required. Instead, by means of the unique and claimed configuration of the probe no incision is necessary. In addition, Applicants invention and configuration is intended to treat the choroid blood supply at the back of the retina and not the ret inal vessels that feed the retina from the front.

In short, Weiss discloses an apparatus for cannulating a retinal vessel from inside the eye. The apparatus consists of a micropipette, micromanipulator and positioner. This apparatus is not truly minimally invasive because the micropipette is delivered inside the eye through a surgical incision in the sclera (See Figures 1 and 6 in particular). A tube 6 is used (fig. 3) for protection of the fragile glass pipette tip from breakage during insertion into the eye through the sclera (col. 3, Ins 50-64). Tube 6 is not a passage guiding the pipette into the operating position. It is the micromanipulator that brings the pipette into the final operating position (when the tip of the pipette is inside a retinal blood vessel).

Applicants have demonstrated that Weiss does not anticipate the claimed inventions of claims 1-4. Applicants have amended claim 1 at two locations to add the word "and" to make the claim read more easily by correcting the grammar. Claims 1-4 are not anticipated by Weiss and are allowable thereover.

b. Rejection of claims 1-8 as being unpatentable over U.S. Patent No. 5,242,449 to Zaleski in view of U.S. Patent No. 6,413,245 to Yaacobi et al.

Applicants traverse the rejections of claims 1-8 on the basis of the proposed Zaleski-Yaacobi et al. combination.

First, as with the discussion of the previous rejection of anticipation, Applicants do not recite a "passage" configured to conform to the curvature of the eye, but a probe configured to do so.

Zaleski discloses a surgical ophthalmic instrument being introduced in the eye through a surgical incision and capable of performing various functions within the eye, including, for example, breaking up of the natural lens of the eye during catar act surgery, irrigating the eye and aspirating the natural lens particles and irrigation fluid from the eye. Drug delivery as a function of the instrument is not mentioned nor is it suggested in Zaleski. It is not the intended use of the Zaleski instrument and thus Zaleski is not relevant to the present examination.

Yaacobi discloses an apparatus for delivering a drug formulation on the outer surface of the sclera. The apparatus includes a cannula having and a radius of curvature substantially equal to a radius of curvature of the globe of the eye and having a blunt distal tip.

It is thus proposed to combine the teachings of an apparatus intended for insertion through an incision into the eye itself, an apparatus that does not suggest drug delivery therewith, with an apparatus intended for surface delivery of drugs. There is no suggestion that any one of ordinary skill in the art would propose to combine the teachings of two medical instruments used in such disparate ways and for such disparate purposes. Applicants respectfully submit that only through hindsight viewing of Zaleski and Yaacobi et al. in view of the teachings of Applicants' invention would one of ordinary skill in the art look to combine the teachings of the cited and applied patents. The combination of Zaleski and Yaacobi et al. to reject Applicants' claims is thus untenable.

More specifically, Applicants recite in claim 1 that its claimed apparatus includes:

> "a therapeutic agent delivery apparatus .... movable between a retracted inoperative position within said probe and an extended operational position when said distal probe end is disposed adjacent the sclera of an eye suffering from macular degeneration wherein movement of said delivery apparatus from the inactive to the operational position enables the therapeutic agents to be dispensed from said reservoir through said distal probe opening into the eye for the treatment of macular degeneration."

Zaleski discloses an instrument having a slider designed to move the probe from inactive back position to an active, forward position. But both the function and the design of the Zaleski slider are different from Applicants'.

The function of the Zaleski sliding probe is to enable the surgeon to reach different sites of the operation field interior to the eye by advancing the distal end portion 29 of the inner member 21 back and forth and rotating it around the straight rigid tube 27 that serves as a guide for the inner member 21. This feature of the design enables the operator to make irrigation and aspiration in the whole operation field around the straight rigid tube 27.

In a relaxed condition the distal end portion 29 of the inner member has a curved configuration. It can be of various materials, such as a deformable elastomeric or polymeric material with silicone being preferred. Being soft, it cannot serve as a needle and cannot pierce sclera. Its intended use is aspiration of fluids and small particles from the eye through the distal end hole 33.

The main function of the two position slider in Applicants' invention is to advance the needle through the sclera inside the eye into the operating position from the position outside the sclera. The needle is made of a metal and is sharp enough for piercing the sclera. Also, by design, the movement of the needle is performed on a strictly predetermined depth. It penetrates the sclera on a necessary depth only (about 0.75 – 1.0 mm) not to damage the blood vessels of the choroid. In a relaxed condition Applicants' needle has a straight configuration.

The Zaleski probe is straight. In applicants' device the prove is curved and thus so is the passage contained therein. As Applicants needle advances into the forward

position, it is being bent by a curved segment of the probe passage to change its direction and move into the sclera. Zaleski's instrument tip does not function in such a manner.

As noted above, Yaacobi et al. discloses an apparatus for delivering a drug formulation on the outer surface of the sclera. The apparatus includes a cannula having a radius of curvature substantially equal to a radius of curvature of the globe of the eye and having a blunt distal tip.

The examiner states that it would be obvious to modify the probe as taught by Zaleski with the eye conforming probe as taught by Yaacobi et al for the purpose of delivering ophthalmic agents to the back of the eye proximate to macula. Applicants' submit such a combination does not teach Applicants invention as recited in claims 1 -8 for all of the foregoing reasons. In particular, such a combination certainly does not teach the use of a needle to pierce the sclera for delivery of a drug nor that the passage through which the needle travels redirects the direction of the needle as it is advanced and retracted.

Applicants submit that any proposed combination of the Zaleski-Yaacobi devices, one of which has a soft silicone probe used mainly for aspiration from the eye, and another has a blunt tip probe delivering drugs to the back of the eye outside the sclera, cannot produce a drug delivery apparatus with a sharp metal needle piercing the sclera on a predetermined depth and delivering drugs right into the vicinity of the choroid.

On the basis of all of the foregoing arguments Applicants submit that claims 1 -8 are allowable over the cited and applied art.

PETITION FOR TIME EXTENSION

The mailing date of the Office action was March 31, 2006. The three month response date was June 31, 2006. Applicant previously submitted a Response on August 14, 2006 via EFS-Web and paid for a two month time extension. As this Response is being submitted prior to August 31, 2006 and within the one month time period provided in the Notice of Non-Compliant Amendment, Applicants believe that the proper time extension has already been requested and paid. Should Applicants be in error they hereby request such time extension as is necessary to make this Response timely.

The Office is authorized to charge Deposit Account 502417 for any deficiency in such payment for a time extension and to credit any overpayments thereto.

CONCLUSION

Applicant respectfully requests that this Preliminary Amendment be entered and that pending claims 1-8 be allowed.

Respectfully Submitted,

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